J Neurosurg Spine 5:500–507, 2006

Quality of life of lumbar stenosis–treated patients in whom the X STOP interspinous device was implanted

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Object. This study was conducted to compare the quality of life (QOL) in patients with neurogenic intermittent claudication (NIC) secondary to lumbar spinal stenosis (LSS). Using the 36-Item Short Form (SF-36) questionnaire, the authors compared the results obtained in patients treated with the X STOP Interspinous Process Decompression (IPD) System with those obtained in patients who underwent nonoperative therapies.

Methods. Patients with LSS were enrolled in a prospective 2-year multicenter study and randomized either to the X STOP or nonoperative group. The SF-36 survey was used to assess the QOL before treatment and at 6 weeks, 6 months, 1 year, and 2 years posttreatment. An analysis of variance was used to compare individual pre- and posttreatment mean SF-36 domain scores between the two groups and within each treatment group.

At all posttreatment time points, the authors observed the following: 1) mean domain scores in X STOP–treated patients were significantly greater than those in patients treated nonoperatively, with the exception of the mean General Health (GH), Role Emotional, and Mental Component Summary scores at 2 years; and 2) mean posttreatment domain scores documented in X STOP–treated patients were significantly greater than mean pretreatment scores, with the exception of mean GH scores at 6, 12, and 24 months.

Conclusions. The results of this study demonstrate that the X STOP device is significantly more effective than nonoperative therapy in improving the QOL in patients with LSS. The results are comparable with those reported in other studies involving traditional decompressive techniques for LSS and suggest that the X STOP implant can provide an effective treatment compared with nonoperative and conventional surgical therapies.

Key Words • neurogenic intermittent claudication • spinal stenosis • lumbar spine • SF-36 • outcome measure • randomized prospective trial • prospective study

Neurogenic intermittent claudication secondary to LSS is a degenerative condition prevalent in the general population 50 years of age and older, and decompressive surgery for LSS is now the most commonly performed spinal surgery in patients age 65 years and over.[6,8] The reported success rates of decompressive surgery vary, reflecting the poor scientific quality of the clinical literature, which consists mostly of uncontrolled, nonrandomized, single-center studies involving physician-assessed outcomes measures. The results of these studies are difficult to interpret and even more difficult to compare with those reported in other published studies.

Condition-specific outcomes measures in which patients assess their own outcomes should result in a more

Abbreviations used in this paper: ANOVA = analysis of variance; BP = Bodily Pain; GH = General Health; LSS = lumbar spinal stenosis; MCS = Mental Component Summary; MH = Mental Health; PCS = Physical Component Summary; PF = Physical Functioning; QOL = quality of life; RE = Role Emotional; RP = Role Physical; SF = Social Function; SF-36 = 36-Item Short Form Health Survey; ZCQ = Zurich Claudication Questionnaire.

accurate assessment of the clinical benefit of treatment by removing the possible bias of the treating physician. The ZCQ, also referred to as the Swiss Spinal Stenosis Survey, is a condition-specific questionnaire designed and validated for patients with LSS.[7,22,26,27] Because of its relatively recent introduction, however, few published studies have reported results measured using the ZCQ.

The SF-36, on the other hand, has been widely used in a variety of orthopedic studies, allowing comparisons across a broad range of medical conditions and therapies.[19,30] Well-designed, prospective clinical studies typically include both a condition-specific survey to assess the direct benefit of the treatment, as well as a general health survey to assess the overall benefits provided by the treatment. For example, using the SF-36, Hozack and colleagues[13] and McGregor and Hughes[17] have demonstrated that decompressive surgery improves the QOL in patients with LSS.

The present study was designed to compare the QOL outcomes in patients with LSS treated with a new device, the X STOP Interspinous Process Decompression System (St. Francis Medical Technologies, Inc., Driebergen, The Netherlands), with those obtained in patients who underwent nonoperative therapy. Nonoperative therapy was chosen as a control modality, both because it is a common treatment for mild to moderate neurogenic intermittent claudication and because implantation of the X STOP device, similar to nonoperative care, does not require a highly invasive procedure.

The specific aims of the current study were to 1) compare the QOL in the X STOP–treated patients with that in the nonoperatively treated patients, and 2) compare the results of both X STOP– and nonoperatively treated patients in the present study with results reported in studies of other spinal procedures in which investigators used the SF-36. We hypothesized that 1) the posttreatment SF-36 scores obtained in the X STOP–treated patients would be significantly greater than those in patients who underwent nonoperative therapy and 2) the benefits of X STOP–based therapy would be comparable to those reported in conjunction with lumbar decompression in the treatment of LSS.

Clinical Material and Methods

Patient Selection

Investigators from eight community hospitals and one teaching hospital treated 191 patients between June 2000 and July 2001. Patients were randomized either to the X STOP or nonoperative treatment groups in a prospective controlled trial. The study was conducted under a Food and Drug Administration–approved Investigational Device Exemption and was approved by the institutional review board at each participating institution prior to initiation. All patients signed an institutional review board–approved informed consent form prior to participating in the study.

Patients were eligible for inclusion if they were 50 years of age or older, had symptoms of radiographically confirmed one- or two-level LSS, and had leg, buttock, or groin pain, with or without back pain, that could be relieved during flexion. Patients had to be able to sit for 50 minutes without pain, walk 50 feet or more, and have completed at least 6 months of nonoperative therapy. Primary exclusion criteria included a fixed motor deficit, cauda equina syndrome, significant lumbar instability, previous lumbar surgery, significant peripheral neuropathy or acute denervation secondary to radiculopathy, a scoliotic Cobb angle greater than 25˚, spondylolisthesis greater than Grade I (score range I–IV) at the affected level, presence of pathological fracture(s) or severe osteoporosis of the vertebra(e) and/or hip(s), obesity, active infection or systemic disease, Paget disease or metastasis to the vertebrae, or steroid use for more than 1 month within 12 months preceding the study.

Patients were randomized either to the X STOP or nonoperative group using block randomization by surgical center. An individual not involved in the treatment or care of the patients performed the randomization and informed the surgeon of its result. Patients randomized to the nonoperative group received an epidural steroid injection on enrollment and were eligible for additional injections as needed, as well as nonsteroidal antiinflammatory drugs, analgesic agents, and physical therapy. Physical therapy consisted of education on back care and modalities such as ice packs, heat packs, massage, stabilization exercises, and pool therapy. Braces such as abdominal binders and corsets were permitted, but body jackets and chair back braces were not.

X STOP Operative Technique

The patient was placed on a radiolucent table in the right lateral decubitus position and asked to flex his or her spine (Fig. 1). After the operative level(s) was/were confirmed fluoroscopically, the patient received a local anesthetic; general anesthesia was not typically required. A midsagittal incision of approximately 4 cm was made over the spinous processes of the stenotic level(s), and the musculature was dissected to the level of the laminae and facet joints. Hypertrophied facet joints could be partially resected to ensure that anterior placement of the implant would be feasible. A curved dilator was inserted in the anterior margin of the interspinous space to pierce the interspinous ligament, and a sizing distractor was then inserted to determine the appropriate implant size. The X STOP (Fig. 2) was secured to the insertion instrument and placed in the interspinous space. An adjustable wing was fastened to the implant and was then positioned as close to the spinous process as possible.

Outcomes Assessment

All SF-36 data were collected prior to the initial treatment and then at 6 weeks, 6 months, 1 year, and 2 years following the initial treatment.[19,30] The SF-36 questionnaire is a validated general health outcomes measure developed to assess and compare the general health status of patients. General health outcomes measures are useful when comparing the relative burden of different diseases or the relative benefit of different treatments. The questions and domains of the SF-36 were developed to be nonspecific in terms of age, disease, or treatment group. The questionnaire is composed of eight domains of the most frequently represented health concepts, and each domain

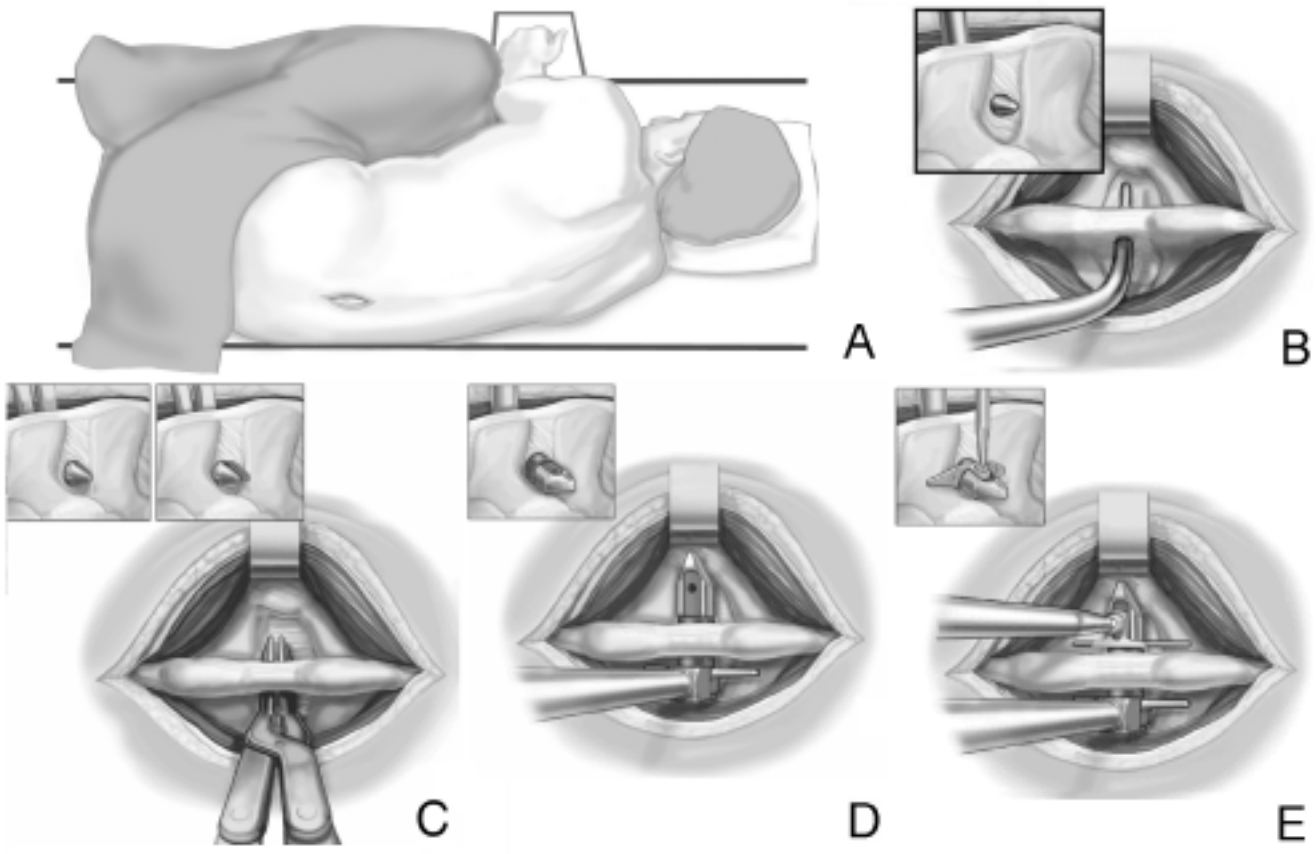

FIG. 1. Sketches illustrating the X STOP surgical technique. A: The patient is placed on the surgery table in the flexed, right lateral decubitus position, and a small incision is made over the spinous processes of the stenotic level(s). B: The musculature is dissected to the level of the facet joints and laminae, and a curved dilator is used to pierce the anterior margin of the interspinous ligament. C: An adjustable sizer is placed in the rent created by the curved dilator and is used to size the interspinous space. D: The X STOP is placed in the anterior interspinous space. E: A universal wing is attached to prevent the implant from migrating within or out of the interspinous space.

contains between two and 10 questions. Physical Functioning addresses the presence and severity of a patient's physical limitation, and the RP domain pertains to health-related limitations in the type or amount of work a patient can perform. Bodily Pain involves the frequency and magnitude of the pain, and the GH domain patients' assessments of their overall health. Vitality is a measure of a patient's energy level and SF is used to assess health-related effects on social activities. Role Emotional measures the impact of emotional problems on work and other daily activities, and MH includes questions from each of the four major mental health dimensions: anxiety, depression, loss of behavioral or emotional control, and psychological well-being. The physical domains such as PF, RP, and BP are often responsive to the benefits of surgery, and the mental health domains are more responsive to treatments for mental disorders.[29] The eight domains can also be combined into two aggregate domains: the PCS and the MCS. These aggregate domains provide a summary of the patient's physical and mental status.

Statistical Analysis

Using an ANOVA, individual pre- and posttreatment

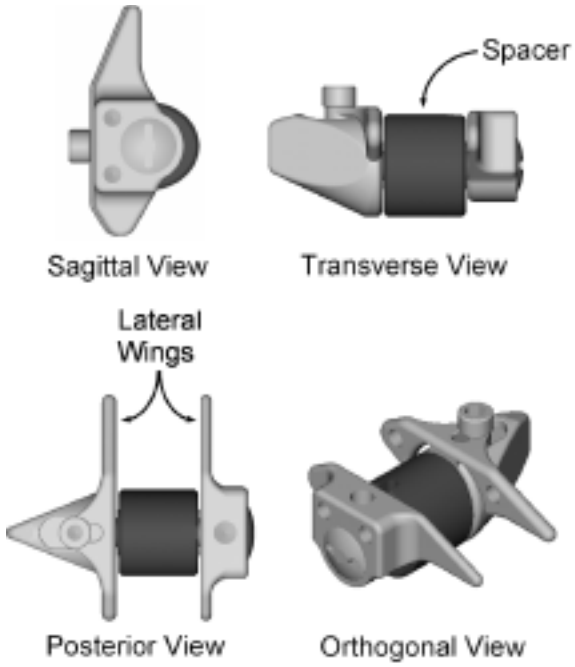

FIG. 2. A schematic of the sagittal, transverse, posterior, and orthogonal views of the X STOP device.

TABLE 1

Summary of demographic data in patients with LSS treated with the X STOP

	Treatment Group		
	X STOP	Nonop	p Value*
age (yrs)	70.0	69.1	0.513
M/F ratio (%)	57:43	52:48	0.387
height (cm)	171	169	0.117
weight (kg)	80.4	81.4	0.569
pain duration (yrs)	3.5	4.7	0.628
employed (%)	33	30	0.643
Workers' Compensation (%)	4	2	0.685

* According to an ANOVA.

mean SF-36 domain scores were compared between X STOP and nonoperative groups. Using an ANOVA, mean SF-36 domain scores were compared at each time point within a treatment group. An intent-to-treat analysis was performed at the 2-year time point for the X STOP and nonoperative groups and compared with the 2-year results reported in other studies. Statistical significance was set at a probability value less than 0.05.

Results

Demographic Data

Of 191 treated patients enrolled in this study, 100 were randomized to the X STOP group and 91 to the nonoperative group. The age, height, and weight of patients in the two groups were similar (Table 1). Sixty-four percent of the X STOP–treated patients and 80% of the nonoperatively treated patients were treated for single-level stenosis. In the X STOP group, 89% of the patients underwent implantation of the device at the L4–5 level and 43% at L3–4; treatment of no other level exceeded 5% of the cases.

The 2-year follow-up SF-36 data were analyzed for 82 X STOP–treated patients and 53 nonoperatively treated patients; four patients in the X STOP group died of causes unrelated to the implant, in one the implant was removed without further surgery, six underwent a laminectomy, six failed to complete the questionnaire, and one withdrew from the study. In the nonoperative group, three patients died of causes unrelated to the treatment, 24 underwent a laminectomy, six failed to complete the questionnaire, and five withdrew from the study.

TABLE 3

*Summary of probability values determined by comparing mean SF-36 scores at baseline in the X STOP and nonoperative groups**

Domain	p Value
PF	0.450
RP	0.170
BP	0.164
GH	0.330
VT	0.481
SF	0.167
RE	0.978
MH	0.334
PCS	0.258
MCS	0.603

* According to the Student t-test.

Comparison of X STOP and Nonoperative Results

There were no significant differences between the pretreatment SF-36 scores of either group in any domain (Tables 2 and 3). At all posttreatment time points, the mean domain scores documented in the X STOP group were significantly greater than those in the nonoperative group, with the exception of the mean GH, RE, and MCS scores at 2 years (Tables 2 and 4). There was no significant difference between the intent-to-treat analysis and the 2-year data for both groups. The greatest difference was a decrease of 3.6 points and 5.5 points in SF for the X STOP and nonoperative groups, respectively.

Pretreatment Compared With Posttreatment SF-36 Scores

At all posttreatment time points, the mean domain scores of the X STOP group were significantly greater

TABLE 2

*Summary of pre- and posttreatment SF-36 scores**

SF-36 Score	X STOP Group					Nonop Group				
	Preop	6 Wks	6 Mos	1 Yr	2 Yrs	Pretreatment	6 Wks	6 Mos	1 Yr	2 Yrs
PF	31.7	63.0	61.5	62.5	59.3	33.9	38.9	42.7	42.3	41.4
RP	13.5	47.8	57.5	58.1	51.4	19.5	32.7	29.0	31.4	28.2
BP	24.5	55.8	53.9	56.5	53.8	27.4	34.8	36.2	36.6	34.5
GH	70.2	76.0	73.3	73.2	69.9	67.6	64.4	64.6	64.4	64.5
VT	45.2	61.7	60.5	60.3	58.3	42.9	42.4	43.5	46.4	49.7
SF	58.8	84.0	81.7	83.8	81.2	64.3	67.9	68.9	65.8	70.4
RE	52.0	77.2	78.0	78.3	73.4	52.2	60.8	62.0	57.7	61.7
MH	74.8	81.9	80.2	79.4	79.7	72.4	73.0	70.2	72.0	73.2
PCS	27.8	39.5	40.1	41.1	38.4	28.9	31.1	31.9	32.6	31.2
MCS	51.5	55.6	54.7	54.8	54.3	50.6	51.1	50.4	49.9	52.5

* VT = vitality.

TABLE 4

*Summary of probability values determined by comparing mean SF-36 scores in the X STOP and nonoperative groups, stratified by interval**

SF-36 Domain	Posttreatment p Value			
	6 Wks	6 Mos	1 Yr	2 Yrs
PF	<0.001	<0.001	<0.001	<0.001
RP	0.027	<0.001	<0.001	0.001
BP	<0.001	<0.001	<0.001	<0.001
GH	<0.001	0.008	0.005	0.101
VT	<0.001	<0.001	<0.001	0.030
SF	<0.001	0.001	<0.001	0.014
RE	0.012	0.016	0.002	0.108
MH	<0.001	0.001	0.010	0.019
PCS	<0.001	<0.001	<0.001	<0.001
MCS	0.003	0.015	0.005	0.309

* According to the Student t-test.

TABLE 6

*Summary of probability values of the SF-36 score comparisons over time or the X STOP and nonoperative groups**

SF-36 Domain	Treatment Group	
	X STOP	Nonoperative
PF	0.803	0.851
RP	0.304	0.909
BP	0.822	0.951
GH	0.297	1.000
VT	0.827	0.284
SF	0.761	0.835
RE	0.826	0.945
MH	0.740	0.806
PCS	0.531	0.845
MCS	0.804	0.647

* The single-factor ANOVA was used to compare scores obtained at 6 weeks and 6 months with those obtained at 1 year and 2 years.

than the mean baseline scores, except the mean GH scores at 6 months, 1 year, and 2 years (Tables 2 and 5). At all posttreatment time points, the mean nonoperative domain scores were not significantly different from the mean baseline scores, except the mean PF score at 6 months; the mean RP scores at 6 weeks and 1 year; the mean BP scores at 6 weeks, 6 months, and 1 year; the mean GH scores at 1 year and 2 years; and the mean PCS score at 1 year (Tables 2 and 5).

Changes Over Time

For a given domain, there was no significant difference among the mean SF-36 scores at any follow-up interval in either the X STOP or nonoperative group (Tables 2 and 6).

Results of X STOP Treatment Compared With Laminectomy

Outcome data obtained during a mean follow-up duration of 12.8 months (range 2.5–26.9 months) were available for all six of the X STOP–treated patients and 22 of the control patients who underwent a laminectomy following the initial X STOP or nonoperative treatment, respectively. To compare the two surgical treatments, the pooled results from the laminectomy group (total 28 cases) were compared with the results demonstrated in X STOP–treated patients who did not undergo laminectomy. The mean preoperative SF-36 scores in the X STOP group were significantly greater that those in the laminectomy group (where preoperative scores in the laminectomy group refer to the SF-36 scores immediately preceding the laminectomy surgery) in all domains except RE (Tables 7 and 8). The mean postoperative SF-36 scores in the X STOP group were significantly greater that those in the laminectomy group in all domains (Tables 7 and 8). There was no significant difference between mean changes in the pre- to postoperative SF-36 scores of the X STOP and laminectomy groups in any domain (Tables 7 and 8). The mean postoperative SF-36 scores documented in the laminectomy group were significantly greater than the preoperative scores in all domains except for the GH, RE, MH, and MCS (Table 9).

TABLE 5

*Summary of probability values derived by comparing mean post- and pretreatment SF-36 scores in X STOP and nonoperative groups**

SF-36 Domain	X STOP Group				Nonop Group			
	6 Wks	6 Mos	1 Yr	2 Yrs	6 Wks	6 Mos	1 Yr	2 Yrs
PF	<0.001	<0.001	<0.001	<0.001	0.129	0.037	0.067	0.271
RP	<0.001	<0.001	<0.001	<0.001	0.016	0.287	0.036	0.371
BP	<0.001	<0.001	<0.001	<0.001	0.014	0.010	0.011	0.073
GH	0.002	0.308	0.301	0.785	0.116	0.506	0.030	0.043
VT	<0.001	<0.001	<0.001	<0.001	0.380	0.325	0.812	0.814
SF	<0.001	<0.001	<0.001	<0.001	0.797	0.914	0.958	0.413
RE	<0.001	<0.001	<0.001	<0.001	0.357	0.200	0.736	0.930
MH	<0.001	0.030	0.049	0.023	0.831	0.155	0.500	0.649
PCS	<0.001	<0.001	<0.001	<0.001	0.087	0.100	0.043	0.267
MCS	0.001	0.047	0.031	0.031	0.589	0.606	0.296	0.609

* According to single-factor ANOVA.

TABLE 7

Summary of the mean changes in baseline SF-36 scores in the X STOP– and laminectomy-treated patients

SF-36 Domain	SF-36 Score: X STOP Group			SF-36 Score: Laminectomy Group		
	Baseline	2 Yrs	Mean Change	Baseline	Follow Up	Mean Change
PF	32.2	58.9	26.7	20.7	40.0	19.3
RP	14.1	51.5	37.4	3.3	28.6	25.2
BP	25.0	53.8	28.8	18.4	43.4	25.1
GH	70.3	69.9	−0.5	55.8	58.9	3.1
VT	45.9	58.3	12.4	29.2	40.2	11.1
SF	58.8	81.2	22.4	41.4	65.2	23.8
RE	51.8	73.4	21.6	37.8	47.6	9.8
MH	74.4	79.7	5.3	62.7	69.3	6.6
PCS	28.1	38.4	10.3	23.8	33.0	9.2
MCS	51.5	54.3	2.8	44.2	48.0	3.8

Discussion

The SF-36 has been used extensively to determine the health state of a number of populations with orthopedic disorders, including LSS,[2,9,13,17,25,28] low-back pain,[4,5,11,12–15,21,24,25] sciatica,[2,20] scoliosis,[1,13] spondylolisthesis,[25] hip arthritis,[13–15,18] knee arthritis,[3,13,18] shoulder disorders,[10,11,23] and tibial fractures.[16] An advantage of a general health outcomes measure such as the SF-36 over a condition-specific measure is that it permits health-state comparisons not only among groups with the same disease state but also among different diseases, treatments, and patient populations.

Lumbar Spinal Stenosis

Four studies of LSS populations treated surgically contain pre- and postoperative SF-36 scores.[2,15,19,27] The results of these studies, as well as those obtained in the present study, indicate that patients with LSS have similar pretreatment SF-36 scores in each domain. The patient populations reported by Strömqvist, et al.,[25] and McGregor and Hughes[17] seem to have lower baseline SF-36 scores, and the populations studied by Atlas, et al.,[2] seem to have somewhat higher scores; the X STOP and nonoperative population scores lie in between the extremes for most domains. As one might expect, the PF, RP, BP, and the PCS pretreatment scores for a physical disorder such as LSS are the lowest compared with other SF-36 domains. It has also been shown that these same domains exhibit the most improvement following treatment. The results demonstrate that the PH, RP, BP, and PCS domains improve the most following surgical decompression or X STOP implantation, as indicated by a change in the pretreatment domain score to the posttreatment score. The results of the subgroup comparison (laminectomy compared with X STOP implantation) suggest that the X STOP device provides relief similar to that of decompressive surgery in patients with LSS (Tables 7 and 8).

As described by Ware and Sherbourne,[30] the PF, RP, BP, and PCS domains are valid physical health measures that often indicate changes in a patient's physical function. The MH, RE, SF, and MCS domains are valid mental health measures that are often used in studies of mental instability and depression.[29] As shown previously, the greatest domain score changes following X STOP surgery were in the realms that pertain to physical function. The mental health domains showed relatively little change, which would be expected because the implant is not intended to alter a patient's mental state. This trend is reflected in a number of surgical studies in the orthopedic literature.[13,29,30]

Conclusions

The results of this study demonstrate that the X STOP device produces a general health benefit in patients with LSS that is significantly better than conservative treatment. In addition, the treatment is comparable to the benefit resulting from the surgical treatment of LSS. Although evaluation of the SF-36 results suggests that the X STOP implant is comparable to lumbar decompression, the outcomes measures do not reflect the additional benefits offered by the X STOP Interspinous Process Decompression technique. The X STOP procedure is often performed using a local anesthetic, frequently does not require removal of any osseous tissue, and produces relatively little pain compared with other more invasive techniques, and these benefits allow for a faster recovery.

TABLE 8

*Summary of probability values obtained in the X STOP and laminectomy comparisons of mean preoperative, postoperative, and change in SF-36 scores**

SF-36 Domain	SF-36 p Value		
	Preop	Postop	Change
PF	0.006	0.003	0.118
RP	0.021	0.007	0.123
BP	0.008	0.044	0.263
GH	<0.001	0.012	0.263
VT	<0.001	0.001	0.454
SF	0.002	<0.001	0.458
RE	0.073	0.002	0.104
MH	0.002	0.006	0.330
PCS	<0.001	0.024	0.299
MCS	0.001	0.004	0.478

* According to the Student t-test.

TABLE 9

*Summary of probability values obtained when comparing the mean pre- and postoperative SF-36 scores for the laminectomy group**

SF-36 Domain	p Value
PF	0.003
RP	0.001
BP	<0.001
GH	0.296
VT	0.012
SF	<0.001
RE	0.213
MH	0.102
PCS	<0.001
MCS	0.109

* According to the Student t-test.

The beneficial results found in the present study have also been demonstrated in the condition-specific ZCQ completed by the patients.[31,32] These results show that the X STOP provides significant clinical improvement in the symptom severity and physical function in patients with LSS compared with conservative therapy and is comparable with traditional lumbar decompression techniques. The results obtained in the present study indicate that the X STOP not only provides an almost immediate effect, but the effect is sustained for at least 2 years.

Acknowledgments

We thank the staff at each of the participating medical centers and St. Francis Medical Technologies, Inc., for their support.

Disclosure

Drs. Hsu and Zucherman are stockholders in St. Francis Medical Technologies, Inc.

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Manuscript received July 30, 2004.
Accepted in final form June 16, 2006.
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